A DOUBLE-BLIND RANDOMISED 2-ARM, 2-PERIOD CROSSOVER STUDY TO ASSESS THE SIMILARITY OF SAFETY AND PHARMACOKINETICS OF JHL1922 AND PULMOZYME® AFTER SINGLE AND REPEATED ADMINISTRATION IN HEALTHY SUBJECTS

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital respiratory tract disorders
Study type	Interventional

Summary

ID

NL-OMON46758

Source
ToetsingOnline

Brief title
Comparative safety and PK study of JHL1922 and Pulmozyme®

Condition

- Congenital respiratory tract disorders

Synonym
pulmonary disorders

Research involving
Human

Sponsors and support

Primary sponsor: JHL Biotech, Inc., Taiwan
Source(s) of monetary or material Support: Farmaceutische Industrie

Intervention

Keyword: JHL1922, Pulmonary disorders, Pulmozyme®

Outcome measures

Primary outcome

To assess the similarity of safety and tolerability of the test product, JHL1922 (dornase alfa biosimilar), and the reference product, Pulmozyme, at single doses of 2.5 mg and 10 mg of dornase alfa and after 5 days of repeated daily doses of 10 mg, administered per eRapid* nebulizer system.

Secondary outcome

To assess the similarity, if possible, of the systemic levels and sputum levels of dornase alfa after administration of the test product, JHL1922 (dornase alfa biosimilar), and the reference product, Pulmozyme, at single doses of 2.5 mg or 10 mg of dornase alfa and after 5 days of repeated daily doses of 10 mg, administered per eRapid* nebulizer.

Study description

Background summary

JHL1922 is a new compound that may eventually be used to improve pulmonary function in patients with cystic fibrosis (CF). Cystic fibrosis is a genetic disorder in which mucus that is secreted by various body parts is unusually thick. In the lung, this abnormally sticky mucus causes persistent lung

infections and limits the ability of CF patients to breathe over time. Treatment consists of drugs that are inhaled to help clear this thick mucus from the lung, including Pulmozyme®.

The active substance of JHL1922 (and Pulmozyme®) is called *dornase alpha*. Dornase alpha is called *a biological* drug, because it is a large particle made by living cells. Since the active substance of JHL1922 is similar to that of Pulmozyme®, it is expected that the treatment effect of JHL1922 will be very similar to Pulmozyme®, as intended.

Study objective

The purpose of this study is to investigate how safe the new compound JHL1922 is when it is administered to healthy subjects. JHL1922 has not been administered to humans before, but it has been previously tested in the laboratory.

In this study, the safety of JHL1922 will be compared to the safety of Pulmozyme®. Pulmozyme® is already approved and has been marketed to improve pulmonary function in patients with cystic fibrosis since 1993. JHL1922 and Pulmozyme® will first be administered as single dose of 2.5 mg, then after a 7-day gap as a single dose of 10 mg, and then, after a 7 day gap, as once daily doses of 10 mg for 5 days.

This study will also investigate if and how JHL1922 is absorbed and eliminated from the body (this is called pharmacokinetics) in comparison to Pulmozyme®.

Study design

The volunteers will receive JHL1922 and Pulmozyme® in 2 treatment periods (Periods 1 and 2) as a liquid that is vaporized using a nebulizer and inhaled into the lung. One dose consists of 2.5 mg. When taking 10 mg, they will take 4 consecutive doses of 2.5 mg. During administration of the study compound they will sit down in an upright position.

The order in which they receive JHL1922 and Pulmozyme® in Periods 1 and 2 will be determined by chance. Twelve volunteers will receive JHL1922 first followed by Pulmozyme® and the other 12 volunteers will receive Pulmozyme® first followed by JHL1922. Neither the volunteer, nor the responsible doctor knows which order they will get; we call this *the study is blinded*. However, if it is important for the health, for example in case of a serious adverse event, this information can be looked up during the study.

The actual study will consist of 2 periods and during each period the volunteers will have 3 long stays in the research center in Groningen at location Martini Hospital. In each period they will stay in the research center

first for 4 days (3 nights), followed by 3 telephone calls, then again a stay for 4 days (3 nights), followed by 3 telephone calls, and then a stay for 8 days (7 nights), followed by 3 telephone calls. There will be a final follow up visit after Period 2.

Day 1 is the day of first administration (2.5 mg) of the study compound in each period. They are expected at the research center at 11:00 h in the morning (Day -1) prior to the day of first administration of the study compound. They will be dosed on Day 1 and leave the research center on Day 3. They will be contacted by phone in each period on Days 4, 5 and 6.

On Day 7, the volunteers are expected at the research center at 11:00 h in the morning prior to the next administration (10 mg) of the study compound in each period. The study compound will be administered on Day 8. They will then leave the research center on Day 10. They will be contacted by phone in each period on Days 11, 12 and 13.

On Day 14, they are expected at the research center at 11:00 h in the morning prior to the next administration (10 mg) of the study compound in each period. The study compound will be administered once daily on Days 15, 16, 17, 18, and 19. They will then leave the research center on Day 21. They will be contacted by phone on Days 22, 23 and 24.

There are at least 7 days between the last dosing in Period 1 and the first dosing in Period 2.

Intervention

Not applicable.

Study burden and risks

Pain, minor bleedings, bruises, possibly an infection.

Contacts

Public
JHL Biotech, Inc., Taiwan

Shengyi Rd, Zhubei City 302
Taiwan Hsinchu County
TW
Scientific
JHL Biotech, Inc., Taiwan

Shengyi Rd, Zhubei City 302
Taiwan Hsinchu County
TW

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy male/female
18 - 70 years
(BMI) 18 t/m 30 kilograms/meter2
55 - 105 kg
non smokers

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-01-2018
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Pulmozyme®
Generic name:	n.a.
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	08-01-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	26-01-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2017-003514-12-NL
CCMO	NL64478.056.17